UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 21, 2016

PC Code: 098301
DP Barcode: 435243

MEMORANDUM

SUBJECT: **Aldicarb:** Response to Comments Regarding the Preliminary Ecological Risk Assessment for the Registration Review of Aldicarb

FROM: For N.E. Federoff, Wildlife Biologist
James Lin, Environmental Engineer
Environmental Risk Branch 2
Environmental Fate and Effects Division (7507P)

Date: 2017.01.03 12:10:12 -05'00'

JAMES LIN Digitally signed by JAMES LIN Date: 2016.12.22 12:54:13 -05'00'

THRU: Brian Anderson, Chief
Elyssa Arnold, Risk Assessment Process Leader
R. David Jones, Senior Agronomist
Environmental Risk Branch 2
Environmental Fate and Effects Division (7507P)

Date: 2017.01.03 12:23:40 -05'00'

Digitally signed by Arnold, Elyssa Date: 2016.12.22 08:17:44 -05'00'

2016.12.27 12:05:54 -05'00'

TO: Susan Bartow, Chemical Review Manager
Tom Myers, Team Leader
Kevin Costello, Branch Chief
Risk Management and Implementation Branch 4
Pesticide Re-evaluation Division (7508P)

The Environmental Fate and Effects Division (EFED) has reviewed the submitted comments regarding the Preliminary Risk Assessment conducted as part of the registration review of aldicarb (EPA Docket No. EPA-HQ-OPP-2012-0161). The pertinent submitted comments and EFED's responses are listed below.

1. Comments from Cotton Grower Groups

Georgia Cotton Commission, Comment EPA-HQ-OPP-2012-0161-0077

The Environmental Fate and Effects Division (EFED) report suggests modeling concerns for potential risks to birds and mammals. The NCC respectfully notes that the EFED report acknowledges no reports of incidents when aldicarb was used in compliance with label instructions. EFED acknowledged uncertainty due to their understanding of the depth of soil cover after application (Page 2, Table under Label Clarification). The NCC urges EFED to understand it is not easy to label the depth of soil cover due to multiple agronomic variables that dictate seed placement in the soil. Seed placement in the soil will vary by plant species as well as by soil type, soil moisture, rain forecast, and irrigation capabilities within a plant species. However, the placement of the aldicarb with the seed in the seed furrow covered with soil enhances compliance because of desired protection of the seed. The NCC encourages EFED to recognize the historical use that has demonstrated the lack of real risk to birds and mammals when aldicarb is used as label instruction prescribe.

The NCC urges EPA to recognize the use of aldicarb at planting offers little opportunity for impact on honey bee colonies. It is difficult to understand, from a biological and scientific perspective, why EPA would predict a risk to honey bees from an in-furrow application at planting. Although cotton flower development depends greatly on temperature and time (degree days), it typically takes more than 40 days from planting to flower development. The biological efficacy of aldicarb applied in the soil at planting does not persist for this duration of time. Additionally, studies previously provided to EPA have demonstrated that honey bees are not attracted to cotton pollen. Similarly, studies have shown little nectar production in pre-flowering cotton. EPA is urged to refine this risk assessment to reflect these biological data.

CA Cotton Ginners and Growers Associations (CCGGA), Comment EPA-HQ-OPP-2012-0161-0080

CCGGA asks that the EPA recognize that given the minimal risk, worker exposure and benefits of aldicarb and the critical void that has been created since its lack of availability, current alternatives on the market would result in multiple applications to achieve equivalent levels of protection that aldicarb provides. Additionally, our Associations asks that EPA recognize the lack of impact aldicarb in-furrow applications has on honey bee colonies. Given the environment, temperature, time (degree days) and other factors, cotton flower development typically takes more than 40 days. The efficacy of aldicarb applied in the soil at planting does not persist for this duration of time. Additionally, EPA has been provided studies demonstrating that not only are honey bees not attracted to cotton pollen but also that little nectar production in pre-flowering cotton. We would urge EPA to refine the risk assessment to reflect this biological data.

Plains Cotton Growers, Inc., Comment EPA-HQ-OPP-2012-0161-0082

Among the information reviewed was a report from the Environmental Fate and Effects Division (EFED) that suggests concerns for potential risks to birds and mammals. Despite the fact that the EFED report included no reports of harmful incidents when aldicarb is used in compliance with label instructions to support their concern, the authors did acknowledge uncertainty related to their understanding of the depth of soil cover after application. Seed placement in the soil will vary by plant species as well as by soil type, soil moisture, rain forecast, and irrigation capabilities. However, the placement of aldicarb in the seed furrow that is mechanically covered with soil minimizes the potential for exposure to non-target organisms. PCG encourages EFED to recognize the historical use data that demonstrates the lack of real risk to birds and mammals when aldicarb is used according to the current label. PCG also encourages the EPA to also recognize that use of aldicarb at planting offers little opportunity for impact on honey bee colonies. EPA is urged also to refine its risk assessment of aldicarb in regard to honey bees to reflect biological data from studies that show cotton exhibits little nectar production pre-flowering and that honey bees are not strongly attracted to cotton pollen; that flower development in cotton typically takes 40 or more days; and that the biological efficacy of aldicarb applied at planting does not persist for that length of time. Based on the available data, it is clear that aldicarb poses a minimal risk to honey bees and other species and continues to meet the standards for registration under FIFRA when used according to current label instructions. Aldicarb continues to provide cotton producers a safe and effective alternative for control of early season insect and nematode pests and we look forward to its continued availability.

National Cotton Council, Comment EPA-HQ-OPP-2012-0161-0086

The Environmental Fate and Effects Division (EFED) report suggests modeling concerns for potential risks to birds and mammals. The NCC respectfully notes that the EFED report acknowledges no reports of incidents when aldicarb was used in compliance with label instructions. EFED acknowledged uncertainty due to their understanding of the depth of soil cover after application (Page 2, Table under Label Clarification). The NCC urges EFED to understand it is not easy to label the depth of soil cover due to multiple agronomic variables that dictate seed placement in the soil. Seed placement in the soil will vary by plant species as well as by soil type, soil moisture, rain forecast, and irrigation capabilities within a plant species. However, the placement of the aldicarb with the seed in the seed furrow covered with soil enhances compliance because of desired protection of the seed. The NCC encourages EFED to recognize the historical use that has demonstrated the lack of real risk to birds and mammals when aldicarb is used as label instruction prescribe.

The NCC urges EPA to recognize the use of aldicarb at planting offers little opportunity for impact on honey bee colonies. It is difficult to understand, from a biological and scientific perspective, why EPA would predict a risk to honey bees from an in-furrow application at planting. Although cotton flower development depends greatly on temperature and time (degree days), it typically takes more than 40 days from planting to flower development. The biological efficacy of aldicarb applied in the soil at planting does not persist for this duration of time. Additionally, studies previously provided to EPA have demonstrated that honey bees are not attracted to cotton pollen. Similarly, studies have shown little nectar production in pre-flowering cotton. EPA is urged to refine this risk assessment to reflect these biological data.

EFED Responses to Comments from the Cotton Grower Groups

Risks to Pollinators

Aldicarb is considered highly toxic by acute contact exposure to honeybees with an LD_{50} of 0.285 µg/bee. Because of its granular formulation, it is unlikely that there is a direct contact exposure scenario for honeybees. However, other soil dwelling beneficial insects and invertebrates could be exposed to aldicarb and aldicarb residues through contact with the granules. Contact with dissolved residues in puddles and/or with plants (via pollen and nectar) due to its systemic nature is possible. Cotton is attractive to honey bees, bumble bees, and solitary bees under certain conditions (http://www.ree.usda.gov/ree/news/Attractiveness_of_Agriculture_crops_to_pollinating_bees_Report-FINAL.pdf). Under the Tiered approach for pollinator risk assessment, residue studies are among the type of data requested. Therefore, theoretical presumptions regarding residue levels may be tested.

Risks to Birds and Mammals

The over-riding concern for aldicarb is the high risk of mortality to birds and mammals. Aldicarb is very highly toxic to avian and mammalian species. It is a systemic pesticide and a potent cholinesterase (ChE) inhibitor. Acute and chronic RQs for aldicarb can be misleading since it can take the ingestion of only 1 granule for mortality to occur (Balcomb *et al.*, 1984). Supplemental open literature suggests acute oral LD_{50}s of 0.75 mg/kg for passerine species. The mammalian LD_{50} is similar to birds at 0.9 mg/kg. Exposure to aldicarb caused lower survivability and pup weights in offspring of all litters in testing (reproductive LOAEL = 1.4 - 1.7 mg/kg-bw; NOAEL = 0.7 - 0.9 mg/kg-bw). These toxicity values suggest that even if mammals survive acute aldicarb exposure they may suffer adverse reproductive effects from chronic exposure. In addition, since there are risks to birds, risks to reptiles are also possible.

Regarding incorporation, EFED modeled variable incorporation depths and still had risk to terrestrial organisms. Assumptions of incorporation efficiency did not reduce the level of risk to avian and mammalian species below the Level of Concern (LOC). EFED modeled 99% (for banded/sidedress), 99.5% (banded/sidedress and in-furrow) and 99.9% (banded/sidedress and in-furrow) incorporation efficiency at EPA typical application rates to investigate whether such assumptions, albeit unrealistic, would reduce the risk to below LOC for terrestrial wildlife. None of the modeling scenarios decreased the avian or the mammalian risk beyond Agency levels of concern for any of the crops. It is assumed that some amount of granules (even just one) may remain on the surface and that consumption of even a small number of granules may produce mortality.

Incidents

There have been numerous mortality incidents to birds and mammals where aldicarb was determined to be a likely cause. Even though most of the reported incidents were either from the intentional or accidental misuse of aldicarb, very few incidents that occur are reported to the EPA. The number of documented kills is believed to be a small fraction of total mortality caused by pesticides. Mortality incidents must be seen, reported, and have reports submitted to EPA to have the potential for entry into the database. Incidents often are not seen, due to scavenger removal of carcasses, decay in the field, or simply because carcasses may be

ED_005427A_00004977-00003

hard to see on many sites and/or few people are systematically looking. Poisoned animals may also move off-site to less conspicuous areas before dying. Incidents may not get reported to appropriate authorities capable of investigating the incident for a variety of reasons including the finder may not know of the importance of reporting incidents, may not know who to call, may not feel they have the time or desire to call, or may hesitate to call because of their own involvement in the kill. Incidents reported may not get investigated if resources are limited or may not get investigated thoroughly, with residue analyses, for example. Also, if kills are not reported and investigated promptly, there will be little chance of documenting the cause, since tissues and residues may deteriorate quickly. Reports of investigated incidents often do not get submitted to EPA, since reporting by states is voluntary.

2. **Comments from USDA, Comment EPA-HQ-OPP-2012-0161-0081**

Aquatic Exposure
EPA's model results for aquatic exposure are based on Minnesota. However, per the AgLogic 150 label, aldicarb may NOT be applied in Minnesota.

Drinking Water Exposure
Per "Table 1. Screening-Level TTR EDWCs for Proposed Uses of Aldicarb," EPA's surface water source drinking water results for drinking water were derived for sugar beets in Minnesota. However, per the AgLogic 15 G label, aldicarb label may not be applied in Minnesota. USDA seeks a refined assessment more appropriate to the existing label.

Surface Water Refinement
EPA has assumed 100% PCA. Aldicarb began to be marketed as recently as 2016 so the PCA should be refined. The Extension Service was unable to estimate the magnitude of aldicarb adoption for 2016. USDA is available to assist EPA later in this regard. USDA hopes that EPA will be able to refine the assessment using confidential sales information from the registrant. USDA requests the risk numbers be more refined using the Pesticide in Water Calculator (PWC) model instead of the SWCC.

Drinking Water Refinement
USDA believes the surface water values will be much improved when the depth of the furrows are taken into account and also the inches of soil used to cover aldicarb granules by the applicator (to be clarified by the registrant) in furrows and for side-dressings and also if Minnesota were not used as the representative site. Moreover, there are numerous states where aldicarb cannot be applied. Also, the label provides directions for on appropriate actions in areas of vulnerable soils whereas the EPA PRZM-GW assumes "high leaching potential soils."

It appears that Minnesota was used as the basis for the ground water assessment. USDA seeks that the modeling be based on where aldicarb is currently labeled. This would accurately reflect the application time, meteorology, soil types, soil temperatures and pH of where aldicarb is used. EPA's refined assessment should also take into consideration the soil restrictions noted on the label for each listed state beginning on Page 17 of the AgLogic 15G label. USDA notes the label restrictions regarding vulnerable soils to protect groundwater which may be used for drinking water such as: "If AgLogic 15G is applied to cotton as an At-Plant application and a Side Dress application and a vulnerable soil is present and the water table is less than 25 feet below ground surface, do not apply within l000 feet of a drinking water well unless it is known or reasonably believed based upon authoritative sources that such wells are either cased to 1000 feet below ground level or a minimum of 30 feet below the water table. If it is not known whether the water table is greater than 25 feet below ground surface, assume that the water table is less than 25 feet below ground surface."

EFED Responses to USDA Comments

Aquatic Exposure and Drinking Water Exposure:
The Minnesota sugar beets scenario is a surrogate for Minnesota and other areas with similar soils and weather patterns and is not limited to represent only Minnesota.

Surface Water Refinement
The PCA factor is based on EFED's most recent guidance document, which indicates that for All-Ag uses, the value of 1.0 should be used. The guidance "Development of Community Water System Drinking Water Intake Percent Cropped Area Adjustment Factors for use in Drinking Water Exposure Assessments: 2014 Update" is available at: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/development-community-water-system-drinking-water.

Drinking Water Refinement
Typical in-furrow applications are made across the open furrow and not placed at the bottom of the furrow. This causes the granules to be spread through the depth of the furrow when the furrow is closed. This is reflected using CAM = 4 option in PRZM, or the 'uniform' option in PWC. While placing the pesticide at the bottom of the furrow (CAM = 8, or @depth) is possible, it would not be the typical practice unless specific instructions to do so were included on the label. The label modification is required for the farmer to change the nozzle used to release the pesticide, or at least adjust its depth to affect application at the bottom of the furrow to make sure all granules are dropped below the runoff extraction zone. Also with granule applications, dusting-off can be commonly observed and the label also needs to address this aspect.

The ground water estimated concentrations were based on the Florida Central Ridge scenario, which provides the highest concentrations among the six available ground water scenarios. Modeling with the new PWC version 1.52, the ground water concentrations at pH 6, 7, and 8 are presented below:

Modeled Scenario	Ground-water pH	Max. Daily Conc. (µg/L)	Mean Breakthrough Time (yrs)	Post-breakthrough Mean (µg/L)
FL Central Ridge	6	100	3.4	31
	7	33		3.5
	8	1.25		0.002

The differences of the concentrations are due to the influence of the hydrolysis half-life. The half-life values are 152 days, 63 days, and 6 days for pH at 6, 7, and 8, respectively.

To account for the well setback distances, EFED used a plug flow model to simulate the additional travel time for a pesticide to reach a drinking water well from point of application, which is explained in the drinking water assessment. The reduction factor is based on a typical high-end lateral ground water velocity of 1 ft/day as recommended in the PRZM-GW guidance document[1]. A slower flow of 0.1 ft/day is also explored here.

[1] USEPA. 2012. Guidance for Selecting Input Parameters for Modeling Pesticide Concentrations in Groundwater Using the Pesticide Root Zone Model. Version 1.0. U.S. Environmental Protection Agency, Office of Pesticide Programs, Environmental Fate and Effects Division; Health Canada, Pesticide Management Regulatory Agency, Environmental Assessment Directorate. Oct. 15, 2012.

ED_005427A_00004977-00005

At pH 6, the k value (degradation rate in aquifer) is 0.00456/day based on the hydrolysis half-life of 152 days. The effects of well setback at different distances are as follows:

Well Setback (ft)	1 ft/day Ground-water Velocity		0.1 ft/day Ground-water Velocity	
	Max. Daily Conc. (µg/L)	Post-breakthrough Mean (µg/L)	Max. Daily Conc. (µg/L)	Post-breakthrough Mean (µg/L)
50	79.61	24.68	10.23	3.17
300	25.46	7.89	1.14E-4	3.55E-5
500	10.23	3.17	1.25E-8	3.88E-9
700	4.11	1.27	Not calculated	Not calculated
1000	1.05	0.32	Not calculated	Not calculated

At pH 7, the k value is 0.011/day based on the hydrolysis half-life of 63 days. The effects of well setback at different distances are as follows:

Well Setback (ft)	1 ft/day Ground-water Velocity		0.1 ft/day Ground-water Velocity	
	Max. Daily Conc. (µg/L)	Post-breakthrough Mean (µg/L)	Max. Daily Conc. (µg/L)	Post-breakthrough Mean (µg/L)
50	19.04	2.02	0.134	0.0142
300	1.22	0.13	1.53E-13	1.62E-14
500	0.13	0.014	Not calculated	Not calculated
700	1.5E-2	1.5E-3	Not calculated	Not calculated
1000	5.5E-4	5.8E-5	Not calculated	Not calculated

At pH 8, the k value is 0.1155/day based on the hydrolysis half-life of 6 days. The effects of well setback at different distances are as follows:

Well Setback (ft)	1 ft/day Ground-water Velocity		0.1 ft/day Ground-water Velocity	
	Max. Daily Conc. (µg/L)	Post-breakthrough Mean (µg/L)	Max. Daily Conc. (µg/L)	Post-breakthrough Mean (µg/L)
50	3.9E-3	6.2E-6	1.03E-25	1.64E-28
300	1.1E-11	1.8E-18	Not calculated	Not calculated
500	1.0E-25	1.6E-28	Not calculated	Not calculated
700	9.5E-36	1.5E-38	Not calculated	Not calculated
1000	8.4E-51	1.3E-53	Not calculated	Not calculated

3. **Comments from AgLogic Chemical LLC, Comment EPA-HQ-OPP-2012-0161-0083**

MRID 49956504 - Ritter, A. (2016). Aldicarb: Drinking Water Exposure Assessment for Preliminary Risk Assessment – AgLogic Comments, Rebuttal and Revised Modeling.
Considering the application methods currently on the label there should be no contaminated granules available to contribute to exposure via surface water puddles should they form. AgLogic believes that the current AgLogic 15G label application methods pose minimal risk to Nontarget aquatic and terrestrial wildlife due to current cultural practices and disagrees with EPA's conservative conclusions. Despite this, AgLogic is willing to consider potential label modifications to remove the T-band and peanut foliar applications, leaving only the in-furrow application method on the label. With the in-furrow application method, the granular formulation is incorporated at planting, at depth along with the crop seeds, and immediately covered up to a minimum of 1-inch below the soil surface. This meets the aquatic modeling requirement for no potential for aquatic exposure with incorporation of the granule a minimum of 2 cm below the soil surface (i.e., 100% incorporation), consistent with the assumption the Agency made relative to sweet potatoes in the aquatic

assessment. Thus the EECs for all labeled uses are 0 (i.e., no exposure). With no exposure from the in-furrow application method (i.e., EECs of 0), the worst case RQs for all crops would be 0, indicating negligible risk to aquatic and terrestrial organisms.

MRID 49956506 - Hancock, G (2016). AgLogic Response to USEPA Preliminary Ecological Risk Assessment in Support of the Registration Review of Aldicarb

The overall conclusion of this response to the risk assessment is that the weight of evidence based on over 45 years of aldicarb use in the US, the near lack of incident data attributed to label use of aldicarb, highly refined agricultural practices and equipment, the way growers use aldicarb, and state-of-the-art probabilistic aquatic and terrestrial risk assessments that concluded minimal probability of risk, convincingly refute to presumption of risk that has followed all the USEPA ecological screening level risk assessments triggered by the various regulatory actions.

EFED Response to AgLogic Comments on Water Modeling

The exposure to the granular applications is influenced by the locations of the granules (*i.e.*, the placements of the granules), EFED agrees that the registrant's mitigation proposal will reduce the potential exposure by making sure all granules are covered with soil and by removing the foliar peanut applications.

The registrant indicates that the granules are dropped in-furrow immediately before or after the seed drop. A typical in-furrow application is made across the open furrow and not placed at the bottom of the furrow. This causes the granules to be spread through the depth of the furrow when the furrow is closed. This is reflected using CAM = 4 option in PRZM, or the 'uniform' option in PWC. While placing the pesticide at the bottom of the furrow (CAM = 8, or @depth) is possible, it would not be the typical practice unless specific instructions to do so were included on the label. The label modification is required for the farmer to change the nozzle used to release the pesticide, or at least adjust its depth to affect application at the bottom of the furrow to make sure all granules are dropped below the runoff extraction zone.

EFED Response to AgLogic Comments on Ecological Assessment

There have been numerous mortality incidents to birds and mammals where aldicarb was determined to be a likely cause. Even though most of the reported incidents were either from the intentional or accidental misuse of aldicarb, very few incidents that occur are reported to the EPA. The number of documented kills is believed to be a small fraction of total mortality caused by pesticides. Mortality incidents must be seen, reported, and have reports submitted to EPA to have the potential for entry into the database. Incidents often are not seen, due to scavenger removal of carcasses, decay in the field, or simply because carcasses may be hard to see on many sites and/or few people are systematically looking. Poisoned animals may also move off-site to less conspicuous areas before dying. Incidents may not get reported to appropriate authorities capable of investigating the incident for a variety of reasons including the finder may not know of the importance of reporting incidents, may not know who to call, may not feel they have the time or desire to call, or may hesitate to call because of their own involvement in the kill. Incidents reported may not get investigated if resources are limited or may not get investigated thoroughly, with residue analyses, for example. Also, if kills are not reported and investigated promptly, there will be little chance of documenting the cause, since tissues and residues may deteriorate quickly. Reports of investigated incidents often do not get submitted to EPA, since reporting by states is voluntary.

Regarding incorporation, EFED modeled variable incorporation depths and still had risk to terrestrial organisms. Assumptions of incorporation efficiency did not reduce the level of risk to avian and mammalian species below the Level of Concern (LOC). EFED modeled 99% (for banded/sidedress), 99.5% (banded/sidedress and in-furrow) and 99.9% (banded/sidedress and in-furrow) incorporation efficiency at EPA typical application rates to investigate whether such assumptions, albeit unrealistic, would reduce the risk to below LOC for terrestrial wildlife. None of the modeling scenarios decreased the avian or the mammalian risk beyond Agency levels of concern for any of the crops. It is assumed that some amount of granules may remain on the surface and that consumption of even a small number of granules (even just one) may produce mortality.

Regarding the submitted probabilistic aquatic and terrestrial assessments, EFED conducts its assessments with current Agency approved methods. These assessments do not currently use probabilistic methods of risk assessment.

ED_005427A_00004977-00008